1270865

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

January 07, 2005

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: *60/529,276*
FILING DATE: *December 12, 2003*
RELATED PCT APPLICATION NUMBER: *PCT/US04/41596*

UNITED STATES PATENT AND TRADEMARK OFFICE
DEPARTMENT OF COMMERCE

Certified By

Jon W Dudas

Under Secretary
of Commerce for Intellectual Property
and Acting Director of the
Unites States Patent and Trademark Office

Please type a plus sign (+) inside this box → [+]

PTO/SB/16 (5-03)
Approved for use through 4/30/2003. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Willaim H.	Slattery III, M.D.	Los Angeles, California
Claude A.	Vidal	Santa Barbara, California
Russell J.	Redmond	Goleta, California
Byron L.	Moran	Santa Barbara, California

☐ *Additional inventors are being named on the ____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (280 characters max)

SURGICAL INSTRUMENT AND PROCEDURE FOR IMPLANTING SOUND TRANSDUCER PROXIMATE TO PATIENT'S OUTER EAR CANAL

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

☒ Customer Number **27224** → *Place Customer Number Bar Code Label here*

OR *Type Customer Number here*

☒ Firm or Individual Name	Arthur Freilich				
Address	9045 Corbin Avenue, Suite 260				
Address					
City	Northridge	State	CA	ZIP	91324
Country	USA	Telephone	818-678-6408	Fax	818-678-6411

ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 22 ☐ CD(s), Number

☒ Drawing(s) *Number of Sheets* 10 ☐ Other (specify)

☐ Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT *(check one)*

	FILING FEE AMOUNT ($)
☒ Applicant claims small entity status. See 37 CFR 1.27.	$80.00
☐ A check or money order is enclosed to cover the filing fees	
☐ The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number:	
☐ Payment by credit card. Form PTO-2038 is attached.	

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☐ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted, Date 12/11/2003

SIGNATURE

TYPED or PRINTED NAME Arthur Freilich

TELEPHONE 818-678-6408

REGISTRATION NO. *(if appropriate)* 19,281

Docket Number: 203/524 MB-105

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

16523 U.S.PTO

PTO/SB/17 (10-03)
Approved for use through 07/31/2006. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) $80.00

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	William W. Slattery III, M.D.
Examiner Name	
Art Unit	
Attorney Docket No.	203/525 MB-105

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 501232

Deposit Account Name: Freilich, Hornbaker & Rosen

The Director is authorized to: *(check all that apply)*

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additonal fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	80.00

SUBTOTAL (1) ($) $80.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims		Fee from below	Fee Paid
Total Claims	-20** =	0	X =	0.00
Independent Claims	-3** =	0	X =	0.00
Multiple Dependent			=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) $0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non - English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR § 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Statement	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) ($)

SUBMITTED BY				Complete *(if applicable)*	
Name *(Print/Type)*	Arthur Freilich	Registration No. *(Attorney/Agent)*	19,281	Telephone	818-678-6408
Signature				Date	12/11/2003

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

TITLE: SURGICAL INSTRUMENT AND PROCEDURE FOR IMPLANTING SOUND TRANSDUCER PROXIMATE TO PATIENT'S OUTER EAR CANAL

INVENTOR: WILLIAM H. SLATTERY III, MD., CLAUDE A. VIDAL, RUSSELL J. REDMOND, BYRON L. MORAN

FIELD OF THE INVENTION

[0001] This invention relates generally to hearing aid systems and more particularly to an implantable hearing aid device and compatible instrument and procedure for implanting the device to project sound energy into a patient's outer ear canal.

BACKGROUND OF THE INVENTION

[0002] U.S. provisional application 60/424,912 filed on November 8, 2002, which is incorporated herein by reference, describes a hearing aid system including an implant configured for placement in a recess formed between a patient's retro-auricular space and outer ear canal. The implant is described as comprising a case containing an antenna, electronic circuitry, and a transducer. The transducer functions to convert electrical signals supplied from the implant electronic circuitry into sound energy for projection into the patient's ear canal.

[0003] The hearing aid system of application 60/424,912 also includes an external module including a microphone, electronic circuitry and an antenna. Sound energy picked up by received by the external microphone produces an output signal which is processed by the external module electronic circuitry and transmitted by a telemetry link, preferably RF, to the implant. The signal received by the implant may then be further

processed by the implant electronic circuitry to cause the implant transducer to project sound energy into the patient's outer ear canal.

[0004] U.S. provisional application 60/462,265 filed on April 12, 2003, which is incorporated herein by reference, describes an implantable percutaneous device, and method of implantation, especially configured to promote soft tissue ingrowth for creating an infection resistant barrier and for anchoring the implanted device in place.

SUMMARY OF THE INVENTION

[0005] The present invention is directed to a hearing aid system, including an implantable device ("implant") and a surgical instrument for enabling a physician to install the implant in a patient's body in a simple office procedure using only local anesthesia, while minimizing surgical time, trauma and cost. More particularly, the invention is directed to a hearing aid system including a device configured for implantation and anchoring in a subcutaneous recess adjacent to a percutaneous hole opening into a patient's ear outer canal.

[0006] In accordance with a preferred embodiment of the invention, a surgical instrument is provided comprising an elongate shaft having an outer wall surrounding an elongate interior lumen. The shaft distal end is preferably configured with a bevel edge to facilitate advancing the shaft through an incision behind a patient's pinna and through subcutaneous tissue to a position proximate to the patient's outer ear canal.

[0007] In a preferred method of implantation in accordance with the invention, an elongate hole forming tool is inserted through the instrument's

lumen from the instrument's proximal end. The distal end of the hole forming tool preferably has a cutting edge for forming a percutaneous hole opening into the patient's outer ear canal. Alternatively, the hole can be punched by pressing the tool against an anvil temporarily placed into the patient's ear canal.

[0008] Also in accordance with a preferred method of implantation, the implantable device is transported through the lumen to the shaft distal end for anchoring in subcutaneous tissue adjacent to the patient's ear canal. The implantable device preferably comprises a housing, or case, having a peripheral surface carrying at least one fixation arm, or anchor, configured for movement between a retracted position and a deployed position. When the housing is being transported through the lumen, the fixation arm is retained in the retracted position. However, once the housing emerges from the lumen distal end, the arm deploys to engage subcutaneous tissue adjacent to the patient's ear canal to thus anchor the implant.

[0009] In accordance with an important aspect of the preferred surgical instrument, the elongate shaft has an outer wall of noncircular, preferably, oval, cross section. This noncircular cross-section facilitates tapering the shaft distal end to form a flat bevel, or chisel, edge which edge is useful for separating skin from bone as the shaft distal end is advanced from the retro-auricular space to a position adjacent to the patient's ear canal.

[00010] The shaft noncircular outer wall also facilitates the formation of a noncircular lumen. The implantable device housing preferably has a

similar noncircular cross-section enabling the housing to translate along the lumen toward the distal end without rotating.

[00011] The implantable device housing is preferably configured with a laterally oriented shoulder for engaging subcutaneous tissue proximate to the ear canal and with a distally projecting stud for extending percutaneously through the hole opening into the ear canal. In a preferred embodiment, surface areas of the housing, shoulder, and stud carry a porous layer for promoting soft tissue ingrowth.

BRIEF DESCRIPTION OF THE FIGURES

[00012] Figure 1 is a block diagram of an exemplary hearing aid system including an external microphone module and an implantable device having a transducer for projecting sound energy into a patient's ear canal;

[00013] Figures 2A and 2B are perspective views of a preferred implantable device in accordance with the invention respectively viewed from proximal and distal viewing positions and Figure 2C is a horizontal sectional view taken through the device of Figure 2A schematically showing component placement;

[00014] Figure 3 schematically illustrates a patient's ear area depicting the position of the ear canal and indicating the use of a surgical instrument in accordance with the invention for subcutaneously implanting the implantable device so that a sound transducer carried by a distally extending stud can percutaneously extend to the patient's outer ear canal;

[00015] Figure 4A is a side sectional view of a preferred surgical instrument useful in accordance with the invention for surgically forming a

subcutaneous recess between a patient's retro-auricular space and ear canal for accommodating the device shown in Figures 2A, and 2B and Figure 4B is a sectional view taken substantially along the plane 4B-4B of Figure 4A;

[00016] Figure 5A is a side sectional view of the surgical instrument of Figure 4A shown with an optional side handle and with an elongate obturator accommodated in the instrument lumen, Figure 5B is a perspective view illustrating the orientation of the surgical instrument relative to a patient's ear canal for forming a subcutaneous recess and Figure 5C is a side sectional view illustrating how the instruments distal bevel edge functions to separate skin and bone;

[00017] Figure 6A is a side sectional view of the surgical instrument showing a hole forming tool extending through the lumen to the shaft distal end for forming a percutaneous hole opening into the patient's ear canal, Figure 6B is an enlarged side view showing the cutting tip of the hole forming tool of Figure 6A and Figure 6C is an end view of the cutting tip of Figure 6B;

[00018] Figure 7A is a side sectional view showing the surgical instrument distal end positioned adjacent to the patient's ear canal with the ear canal temporarily containing an anvil, Figure 7B is a sectional view of an anvil which can be temporarily inserted into the patient's ear canal, and Figure 7C is a side sectional view showing an alternative hole forming tool extending through the instrument lumen for punching a percutaneous hole opening into the patient's ear canal;

[00019] Figure 8 is a side sectional view of the instrument showing the use of a dilator tool for enlarging and shaping the percutaneous hole;

[00020] Figure 9A is a side view of the surgical instrument which shows the implantable housing of Figures 2A and 2B contained within a protective sleeve and Figure 9B is a side sectional view which shows the housing positioned for transport through the shaft lumen for placement adjacent to the patient's ear canal;

[00021] Figure 10 is a side sectional view of the instrument showing a pusher tool extending through the protective sleeve of Figure 9B for pushing the implant housing through the instrument lumen; and

[00022] Figure 11A is an enlarged side view of the implant housing ejected from the instrument lumen to deploy its fixation arms and to position its stud in the percutaneous hole opening into the patient's ear canal and Figure 11B is a sectional view taken substantially along the plane 11B-11B of Figure 11A.

DETAILED DESCRIPTION

[00023] Attention is initially directed to Figure 1 which illustrates a hearing aid system 10 of the type disclosed in aforementioned US provisional application 60/424,912, which system can advantageously employ the teachings of the present invention. The system 10 includes an implantable device (or "implant") 60 comprising a housing or case 61. The structural aspects of a preferred housing 61 are illustrated in Figures 2A and 2B to be discussed hereinafter. In addition to the implant 60, the system 10 contemplates utilization of an external microphone module 70 capable of

communicating via a telemetry link 76 with an antenna 64 mounted within the implant housing 61. The antenna 64 is coupled to electronic circuitry 72 contained within the housing 61. More particularly, the antenna 64 is coupled to signal processing circuitry 67 via telemetry circuitry 69. The implant housing 61 also includes a power source 66, typically a battery, for supplying power, via power management circuitry 71, to the signal processing circuitry 67 and telemetry circuitry 69. The signal processing circuitry 67 drives an acoustic transducer 65, e.g., a speaker, to produce sound energy 78.

[00024] In typical operation of the system 10 of Figure 1, the external microphone module 70 is worn externally by a patient and converts sound energy to an RF telemetry signal 76 representing audio information in analog or digitally encoded form. This RF signal is transmitted to the implant antenna 64 and coupled to the electronic circuitry 72 for processing. The telemetry circuitry 69 includes a receiver (not shown) to acquire, filter, and process the incoming signal. The antenna 64 may additionally receive charging electromagnetic energy to charge the power source 66. This energy is transmitted via the telemetry circuitry 69 to the power management circuitry 71. The system 10 may also include a remote control device 75, e.g., a hand held controller, which can be used by the patient to supply commands, via antenna 64, to the signal processing circuitry 67 for affecting various operational parameters such as volume, equalization profile, etc.

[00025] Figures 2A and 2B illustrate a preferred implant housing 61 in accordance with the present invention. The housing 61 basically comprises

a hollow structure 100 comprised of a body portion 102 and a distally extending stud 104. The body portion 102 comprises an outer wall defining a peripheral wall surface 105 and a proximal end wall surface 106. The peripheral surface 105 extends from the proximal end wall surface 106 to a lateral shoulder surface 108. Stud 104 extends distally from the shoulder surface 108 terminating distal end wall surface 109. The housing peripheral surface 105 is preferably noncircular, e.g., oval, for mating with a similarly shaped surgical instrument lumen to be described hereinafter. As can be seen in Figures 2A and 2B, the housing surfaces, i.e., peripheral surface 105, lateral shoulder surface 108, and the peripheral surface 110 of stud 104 preferably all carry a layer of porous material 112 for promoting tissue ingrowth for retaining the housing 61 in place after implantation.

[00026] In order to anchor the housing 61 in place prior to adequate tissue growth into the porous layer 112, the housing 61 preferably includes one or more fixation arms or anchors 120. Each arm 120 has a first free end 122 and a second end 124 secured to the housing body portion 102. Each arm 120 is preferably formed of flexible material so it can be pressed to a retracted position against the peripheral surface of body portion 102 or be deployed to a position, as depicted in Figures 2A and 2B, extending outwardly for engaging subcutaneous body tissue as will be described hereinafter.

[00027] Figure 2C schematically depicts a sectional view through the housing 61 to show an exemplary placement of components within the housing. More particularly the housing 61 encloses a sealed internal compartment 125 containing at least one circuit board 126. The circuit

board 126 carries a planar antenna 64 and is connected to a power source 66 in the form of a disc shaped battery. A sound transducer 65 is mounted within the portion of compartment 125 extending into stud 104 for projecting sound energy through stud end wall 109.

[00028] Attention is now directed to Figure 3 which generally illustrates the ear area of a patient, and the position of the patient's ear canal 130. Figure 3 also depicts the distal portion of a shaft 132 of a surgical instrument 134 to be discussed in detail hereinafter. As will be described, the instrument 134 is used to tunnel through the patient's subcutaneous tissue to create a path for transporting the implant housing 61 to a recess adjacent to the ear canal 130. More particularly, as will be discussed hereinafter, in accordance with the present invention, the distal end 136 of shaft 132 is advanced through an incision 138 behind the patient's pinna to form a tunnel 140 extending from the patient's retro-auricular space 142 to an implant site adjacent to the ear canal 130. Thereafter, the instrument 134 is used to transport the implant housing 61 through the tunnel 140 to the implant site such that the implant housing stud 104 can percutaneously extend to the canal 130 for projecting sound energy directly into the patient's ear canal.

[00029] Attention is now directed to Figures 4A and 4B which illustrate a preferred surgical instrument 134 in accordance with the invention useful for forming the tunnel 140 shown in Figure 3 to place the implant housing 61 at a desired position adjacent to the patient's ear canal 130. The instrument 134 is comprised of a handle 144 having a proximal end 146 and a distal end 148. A large bore 150 opens through end surface 151 of the instrument proximal end 146. The bore 150 is countersunk at 152 to communicate with

distally extending passage 154. An elongate tubular shaft 156 is accommodated in the passage 154 and extends distally therefrom to an open distal end 158. The shaft 156 is formed by a peripheral outer wall 160 which envelops an elongate lumen 162.

[00030] The distal 158 of shaft 156 is preferably tapered at 164 to a pointed leading edge 166. As shown in Figure 4B, the shaft outer wall 160 preferably has a noncircular, e.g., oval, cross-section such that the aforementioned 166 forms a flat bevel or chisel edge 170. This edge 170 functions to facilitate advancing the shaft distal end 158 through subcutaneous tissue to the desired implant site, as will be discussed in connection with Figure 5C.

[00031] Attention is now called to Figure 5A which depicts the instrument 134 having an appropriately shaped solid obturator 172 inserted through the bore 150 and lumen 162 and extending to the distal end 158. The obturator 172 is comprised of an enlarged proximal end 173 and a shaft 174 extending distally therefrom. The obturator shaft 174 has a shaft distal end 175 tapered at edge 176 to match the taper 164 of instrument shaft 156. When the obturator 172 is inserted through bore 150, shoulder 177 on the obturator proximal end 173 engages the end surface 151 to precisely match the obturator end taper 176 to the instrument end taper 164 and thus neatly seal the open end 158 of lumen 162.

[00032] Figure 5A also illustrates an optional side handle 180 mounted on the instrument primary handle 134. The side handle 180 is retained on the handle 134, as by a set screw 182 extending into circumferential slot 184.

[00033] In use, with or without benefit of the optional side handle 180, a physician can apply pressure to the handle 134 to advance the bevel edge 170 from the patient's retro-auricular space to the implant site adjacent to the patient's ear canal 130. The flat bevel edge 170 is useful for enabling the physician to separate skin and other tissue 188 (Figure 5C) from bone material, e.g., mastoid bone 190, while minimizing insult to the surrounding area.

[00034] After the tunnel 140 (Figure 3) is formed through the subcutaneous tissue 188 as discussed in connection with Figures 5A, 5B, and 5C, the obturator 172 is withdrawn from the instrument proximal end 146 leaving the instrument 134 in place. The physician then will insert the shank portion 200 of a hole forming tool 202 through the instrument lumen 162 as shown in Figure 6A. The tool 202 preferably has a forward tip 204 configured to cut a hole 206 through skin surrounding the patient's ear canal.

[00035] Alternatively the physician can use a hole forming tool 210 as shown in Figure 7C to punch a percutaneous hole 206 opening into the ear canal. Tool 210 is comprised of a shank portion 212 which is used in conjunction with an anvil 214 to form the percutaneous hole. More particularly in use, the physician will first place the anvil 214 into the patient's ear canal. The anvil 214 is comprised of a handle portion 216 having a shank 218 extending axially therefrom. The shank is preferably externally threaded at 220 for mounting an internally threaded disposable elastomeric tip 222 thereon. The physician will then insert the shank 218and elastomeric tip 222 into the patient's ear canal 130. Thereafter, as

depicted in Figure 7C, the physician will insert the punch tool 210 through the lumen 162 of shaft 156. The punch tool is comprised of a handle 224 having the aforementioned shank 212 extending therefrom toward a small diameter distal end 226. The end 226 is preferably formed to provide a cutting edge (not shown) to facilitate cutting or punching the patient's skin to form a hole 206 opening into the ear canal 130. In use, the physician will with one hand hold the instrument handle 134 while pressing the punch tool handle 224 distally to force the shank distal end 226 through the skin tissue and against the elastomeric tip 208 on handle shank 218.

[00036] Thereafter, the physician will withdraw the hole forming tool (i.e., tool 202 or 210) while leaving the instrument 134 in place. Subsequently, as depicted in Figure 8, the physician will then insert a dilator tool 240 into the instrument lumen 162. The dilator tool 240 comprises a handle 242 and a shaft 244 having a distal tip 246. The diameter of the distal tip of dilator tool shaft 244 is greater than that of punch tool 220 the hole forming tool (202 of 210) thereby enabling the physician to enlarge and shape the hole 206 opening into the ear canal 130.

[00037] With the instrument 134 still in place and with the shaft edge 170 positioned adjacent to the percutaneous hole 206 opening into the ear canal 130, the dilator tool 240 is withdrawn from the proximal end 146 of handle 144. The implant housing 61 (Figures 2A, 2B) carried by a protective sleeve 250 (Figure 9A, 9B) is then inserted into the bore 150 from the handle proximate end 146. The protective sleeve 250 acts to hold the fixation arms 120 in their retracted position, i.e., essentially flat against the surface of body portion 102 and the permeable layer thereon. With the

implant housing 61 and protective sleeve in the handle bore 150, a pusher tool 264 (Figure 10) having a shaft 266 is used to bear against the housing 61 for pushing the housing out of protective sleeve 250 for transport through the lumen 162 to place stud 104 in percutaneous hole 206. The housing 61 and sleeve 250 are configured so that as the housing 61 emerges from the lumen 162 past shaft edge 170, its fixation arms 120 will automatically deploy to their extended position (Figure 11A) to anchor the housing in the surrounding subcutaneous tissue. The deployed arms 120 are adequate to temporarily anchor the implant housing 61 in place. The instrument 134 can then be withdrawn to leave the housing 61 in situ anchored by the deployed arms 120. Subsequently, over several days or weeks, the patient's tissue will grow into the porous layers 112 carried by the housing 61 to permanently anchor the housing 61 and hold stud 104 extending through the percutaneous hole 206 opening into the canal 130. As was previously mentioned, the stud 104 carries the aforementioned sound transducer 65 (Figure 1) thus enabling the sound output of the transducer to be projected directly into the user's outer ear canal.

[00038] From the foregoing, it should now be appreciated that an improved hearing aid system has been disclosed herein which enables the implantation of a hearing aid in a tunnel or recess adjacent to a patient's ear canal for positioning a sound transducer to project sound through a percutaneous hole directly into a patient's outer ear canal. By utilization of the simple instrument and procedure disclosed herein, the described hearing aid can be readily deployed in a physician's office procedure with little or no insult to the tissue adjacent to the ear canal.

[00039] Although a specific embodiment of the invention has been disclosed herein, it should be recognized that variations and modifications will occur to those skilled in the art well within the spirit and intended scope of the invention as defined by the appended claims.

//

//

//

//

//

//

//

//

//

//

//

//

//

//

//

//

//

//

//

//

//

CLAIMS

1. A method for implanting a hearing aid in a patient so as to extend percutaneously into the patient's ear canal, said method comprising:

forming a small incision behind the patient's pinna;

providing an elongate shaft having an outer wall and at least one elongate lumen extending through said shaft;

advancing said shaft through said incision to position the distal end of said shaft proximate to subcutaneous tissue adjacent to said patient's ear canal;

inserting an elongate tool through said lumen to form a percutaneous hole opening into said ear canal;

providing a hearing aid housing having a lateral shoulder and a stud projecting therefrom; and

transporting said housing through said lumen to said distal end to position said shoulder against subcutaneous tissue adjacent to said patient's ear canal with said stud extending percutaneously through said hole opening into said ear canal.

2. The method of claim 1 wherein a porous layer is provided on the peripheral surface of at least a portion of said housing for promoting tissue ingrowth.

3. The method of claim 1 wherein said advancing step includes providing an obturator to close said lumen.

4. The method of claim 1 further including inserting an anvil in said patient's ear canal; and wherein

said step of inserting an elongate tool to form said hole includes advancing said tool to engage said anvil.

5. The method of claim 1 wherein said housing carries at least one anchor configured for movement between a retracted position and a deployed position;

and wherein when said housing is being transported through said lumen said anchor is retracted and when said housing engages said subcutaneous tissue said anchor is deployed to retain said housing adjacent to said hole.

6. The method of claim 5 wherein said housing is mounted in a protective sleeve prior to being transported through said lumen such that said sleeve retains said anchor in said retracted position; and wherein

said mounted shaft retains said anchor in said retracted position while being transported through said lumen; and

removing said sleeve from said housing to enable said anchor to move to a deployed position in engagement with said subcutaneous tissue.

7. The method of claim 1 wherein said step of providing said elongate shaft comprises providing a shaft having a distal end tapering to a flat bevel edge for facilitating the separation of skin from bone.

8. The method of claim 1 wherein said step of providing said elongate shaft includes providing a shaft outer wall having a noncircular cross-section.

9. The method of claim 1 wherein said step of providing said elongate shaft includes providing an elongate lumen having a noncircular cross-section.

//

//

//

//

//

//

//

//

//

//

//

//

//

//

//

//

10. A medical device configured for implantation at a subcutaneous site in a patient's body comprising:

a housing defining an outer peripheral surface;

a porous layer formed on said peripheral surface for promoting soft tissue ingrowth; and

at least one anchor carried by said housing peripheral surface configured for movement from a retracted position to a deployed position for engaging soft body tissue adjacent to said site to retain said housing in place.

11. The device of claim 10 further including a sleeve mounted on said housing for holding said anchor in said retracted position.

12. The device of claim 11 in combination with means for removing said sleeve from said housing for enabling said anchor to move to said deployed position.

13. The device of claim 10 wherein said housing includes a body portion and a stud portion respectively defining longitudinally extending peripheral surface portions and a shoulder between said body portion and said stud portion defining a laterally extending peripheral surface portion; and wherein

said porous layer is formed on said longitudinally and/or laterally extending peripheral surface portions.

14. In combination, a hearing aid housing and an instrument for transporting said housing through a subcutaneous tunnel from a patient's retro-auricular space to an implant site adjacent to the patient's ear canal, comprising:

said instrument including an elongate shaft defining a lumen having an entrance opening and an exit opening, said shaft being adapted to extend through said tunnel to position said lumen exit opening adjacent to said patient's ear canal;

a hearing aid housing configured for insertion through said entrance opening into said shaft lumen; and

a pusher member for pushing said housing through said shaft lumen and ejecting it from said shaft exit opening end at said implant site.

15. The combination of claim 14 wherein said lumen has a noncircular cross-section; and wherein

said housing has a noncircular cross-section corresponding to said lumen cross-section.

//

//

//

//

//

//

//

16. The combination of claim 14 further including:

at least one anchor carried by said housing configured for movement between a retracted position and a deployed position; and wherein

said anchor is held in said retracted position when said housing is in said lumen and is configured to automatically move to said deployed position when said housing is ejected from said shaft exit opening to engage subcutaneous tissue adjacent to said implant site.

17. The device of claim 14 wherein said housing includes a body portion and a stud portion respectively defining longitudinally extending peripheral surface portions and a shoulder between said body portion and a stud portion defining a laterally extending peripheral surface portion; and wherein

a porous layer is formed on said longitudinally and/or laterally extending peripheral surface portions.

18. The combination of claim 14 further including:

an elongate hole forming tool having a shank configured for removable insertion through said shaft lumen to form a percutaneous hole opening into said patient's ear canal.

19. The combination of claim 18 wherein aid hole forming tool shank has a cutting edge at its distal end for cutting said percutaneous hole.

20. The combination of claim 18 wherein said hole forming tool shank has a distal end configured to punch said percutaneous hole.

21. The combination of claim 14 further including:

an elongate obturator having a shank configured for removable insertion through said shaft lumen for closing the distal end of said lumen.

//

//

//

//

//

//

//

//

//

//

//

//

//

//

//

//

//

//

//

ABSTRACT OF THE DISCLOSURE

[00040] A hearing aid system, including an implantable device ("implant"), and a surgical instrument for enabling a physician to install the implant in a patient's body in a simple office procedure using only local anesthesia, while minimizing surgical time, trauma and cost. The implant is configured for implantation and anchoring in a subcutaneous recess adjacent to a percutaneous hole opening into a patient's ear outer canal. A surgical instrument is provided comprising an elongate shaft having an outer wall surrounding an elongate lumen extending through the shaft. The shaft distal end is preferably configured with a bevel edge to facilitate advancing the shaft through an incision behind a patient's pinna to subcutaneous tissue adjacent to the patient's outer ear canal. The implant is then transported through the instrument's lumen to the recess adjacent to the patient's outer ear canal. The implant housing carries fixation arms configured to automatically deploy when the housing emerges from the instrument's distal end for anchoring the housing into subcutaneous tissue.

//

//

//

//

//

//

//

//

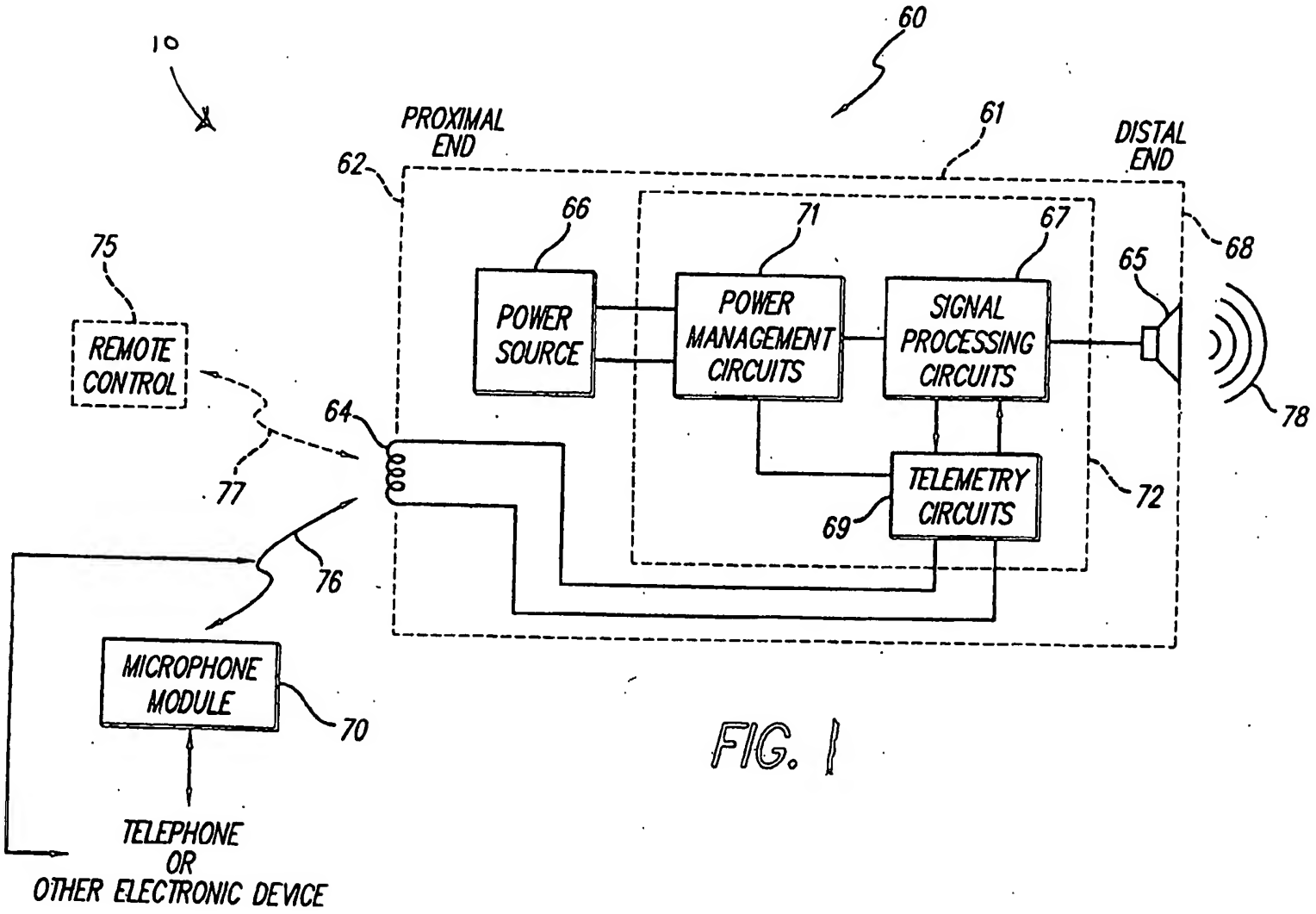
10
60
PROXIMAL END
61
DISTAL END
62
66
71
67
68
75
65
POWER SOURCE
POWER MANAGEMENT CIRCUITS
SIGNAL PROCESSING CIRCUITS
REMOTE CONTROL
64
78
77
TELEMETRY CIRCUITS
72
69
76
MICROPHONE MODULE
70
TELEPHONE OR OTHER ELECTRONIC DEVICE

FIG. 1

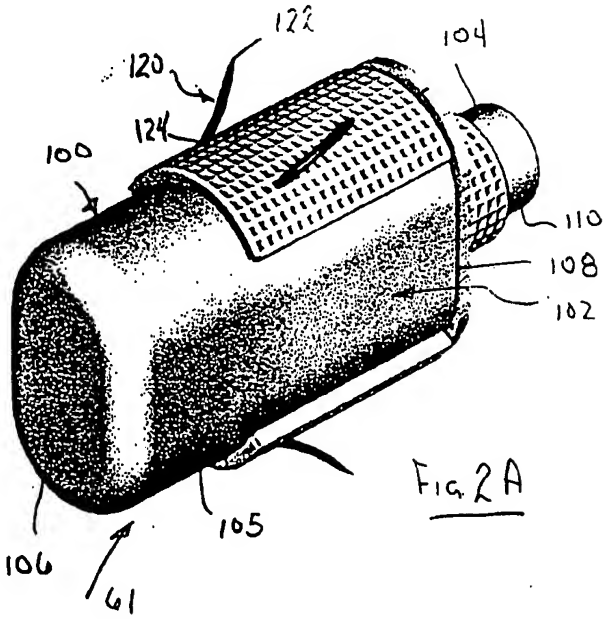

Fig 2A

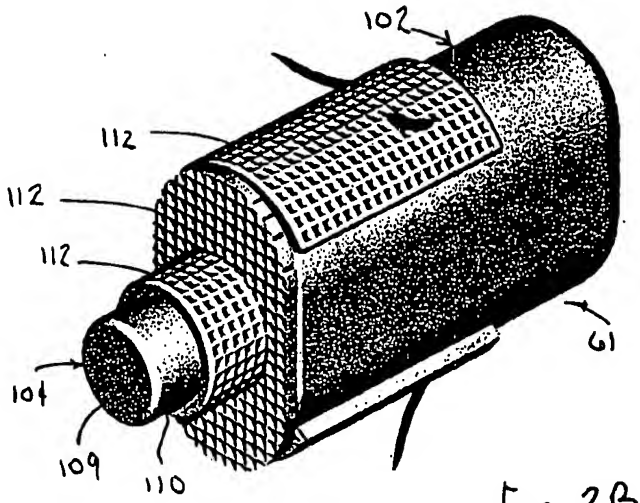

Fig. 2B

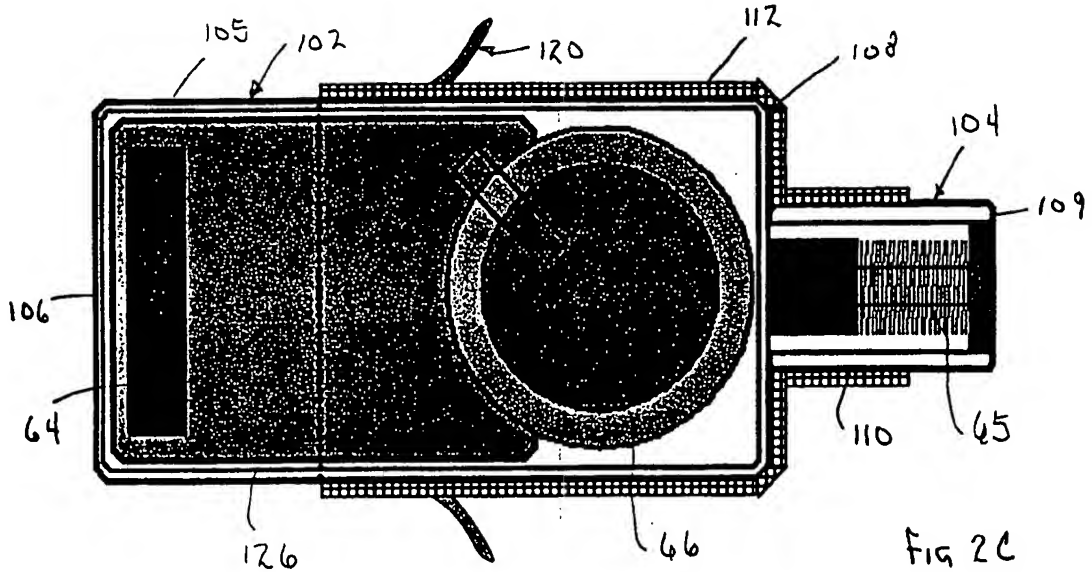

Fig 2C

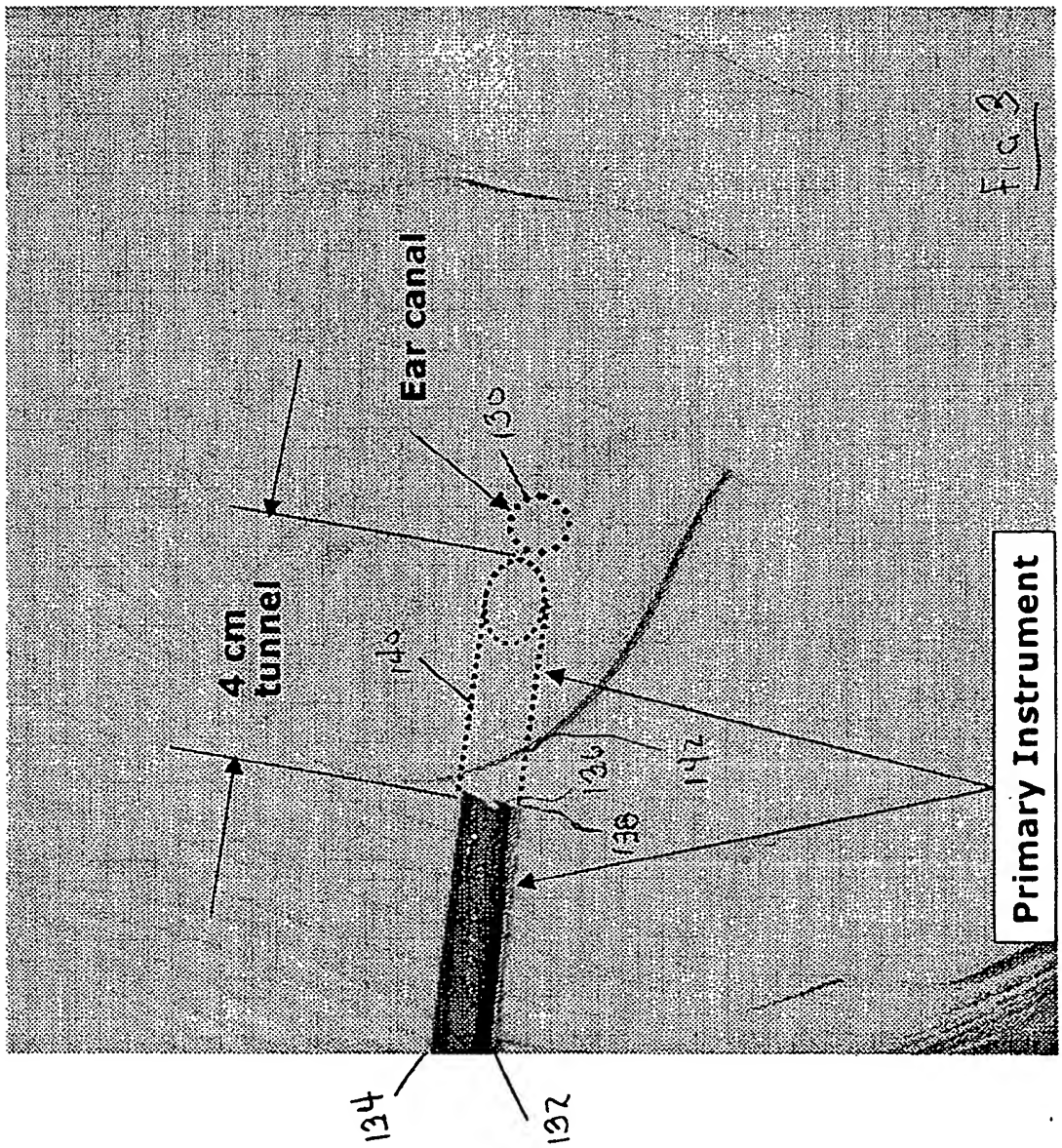
4 cm tunnel
Ear canal
Primary Instrument
134
132
138
136
142
140
130

FIG 3

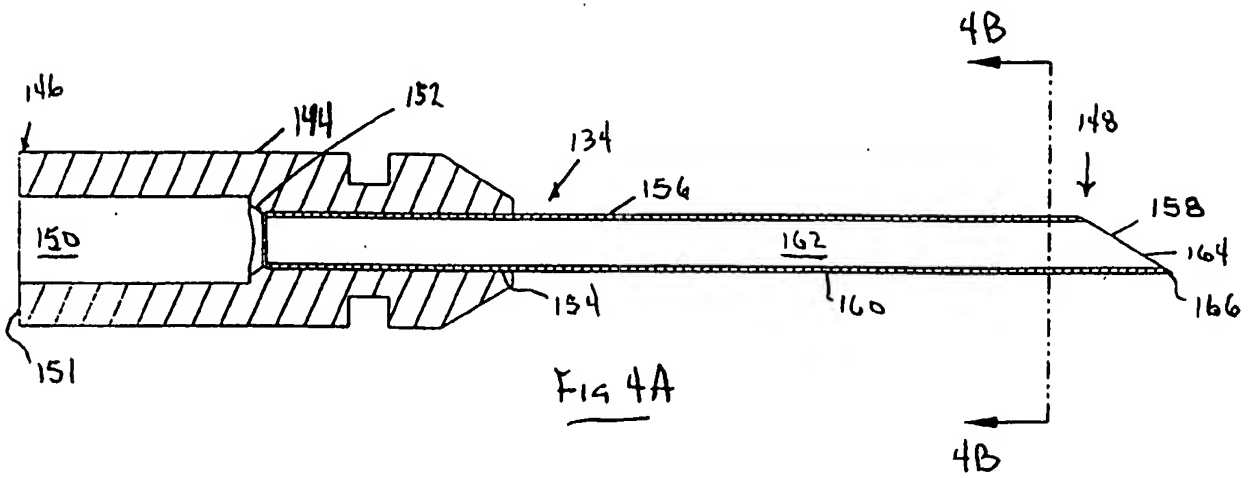
4B
146
144
152
134
148
156
158
150
162
164
154
160
166
151
4B

Fig 4A

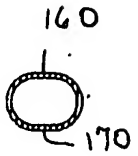
160
170

Fig 4B

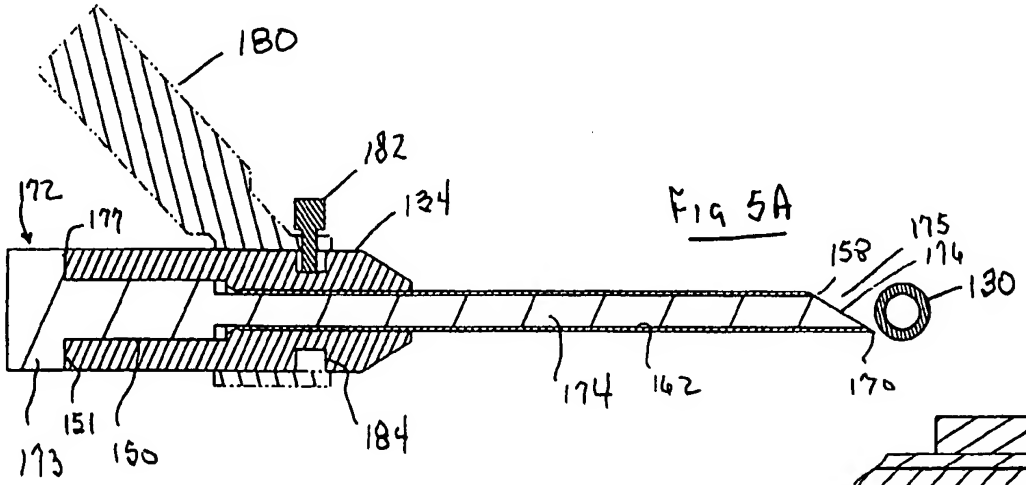

Fig 5A

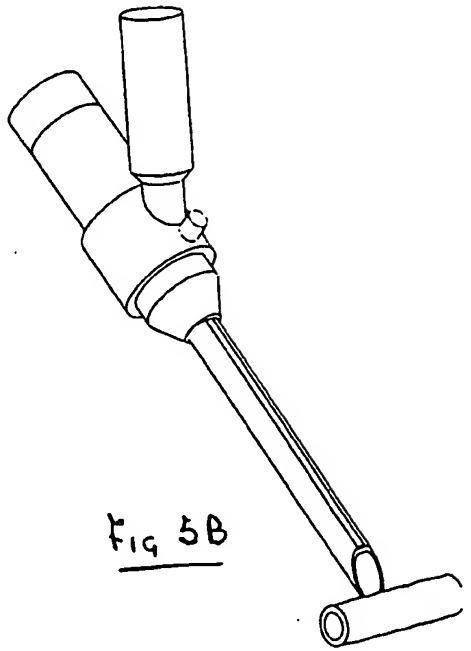

Fig 5B

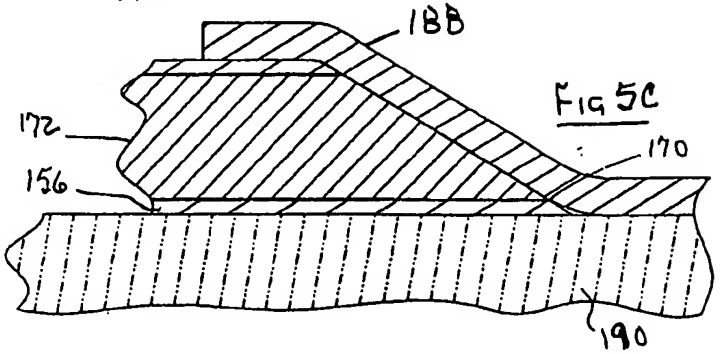

Fig 5C

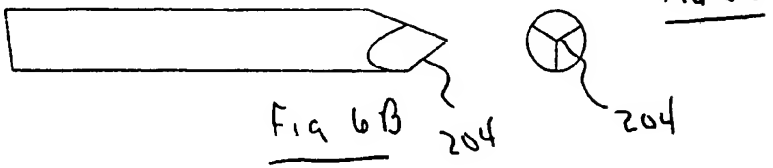

Fig 6C

Fig 6B

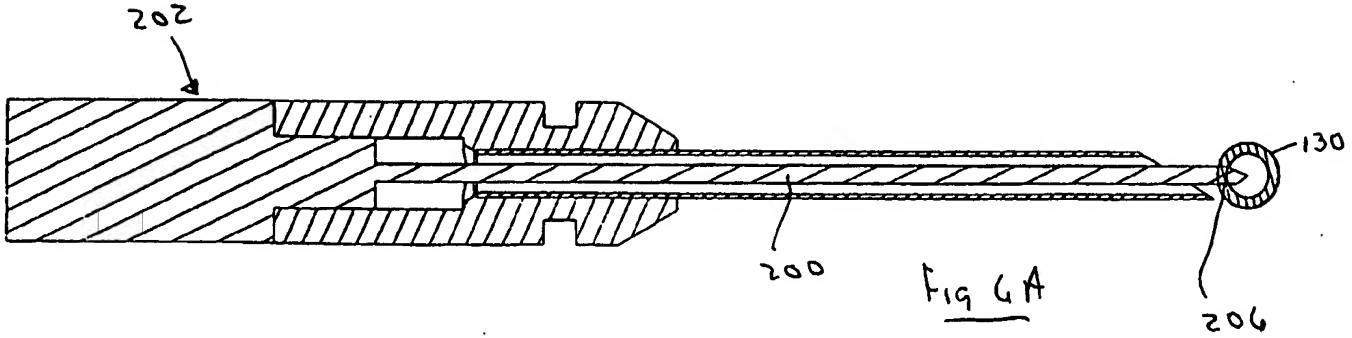

Fig 6A

Without Anvil

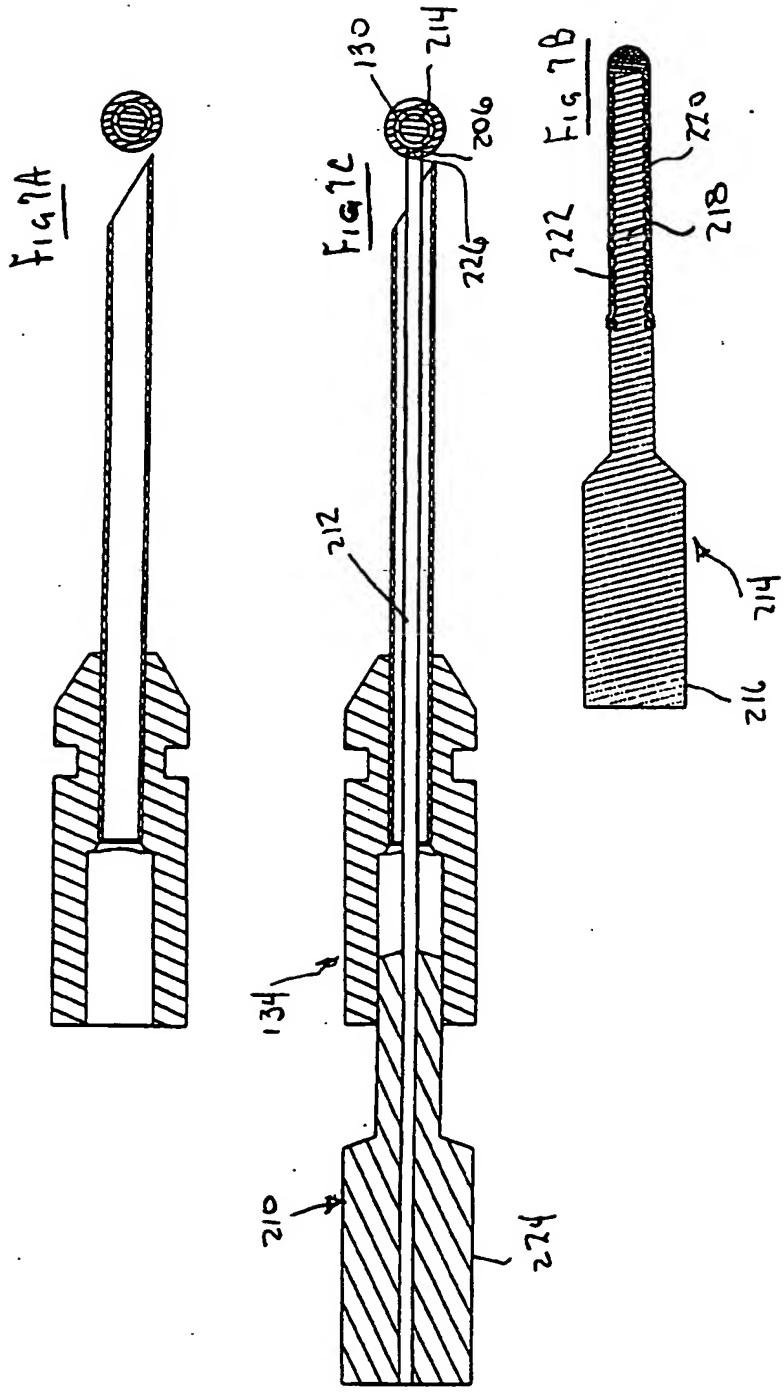
Fig 7A
Fig 7C
130
214
206
226
212
134
210
224
Fig 7B
220
222
218
214
216

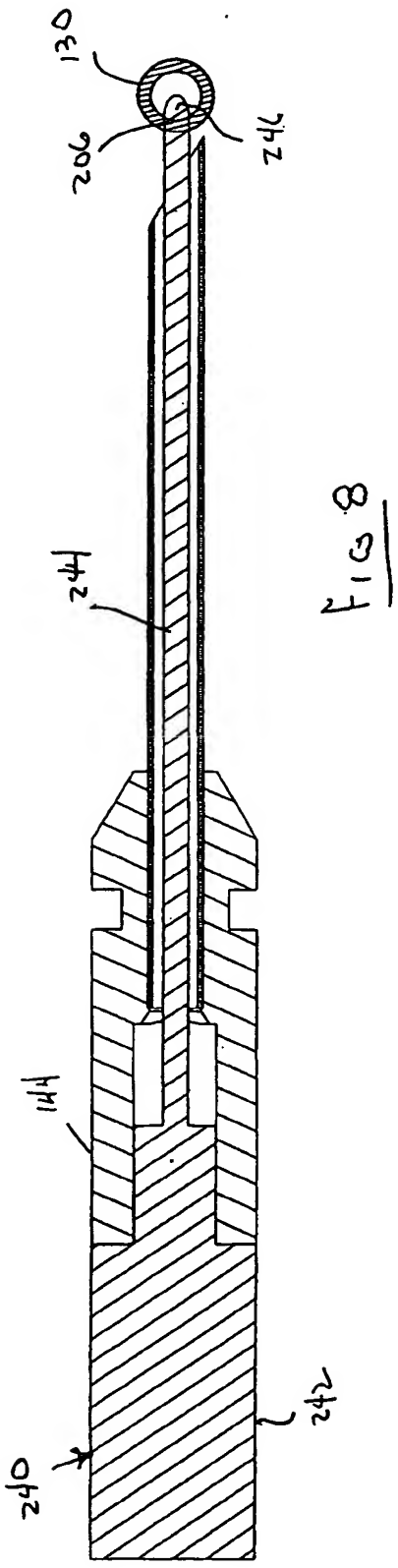

FIG 8

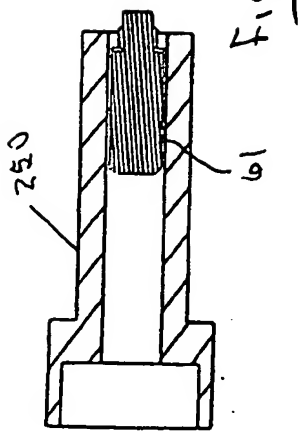

Fig 9A

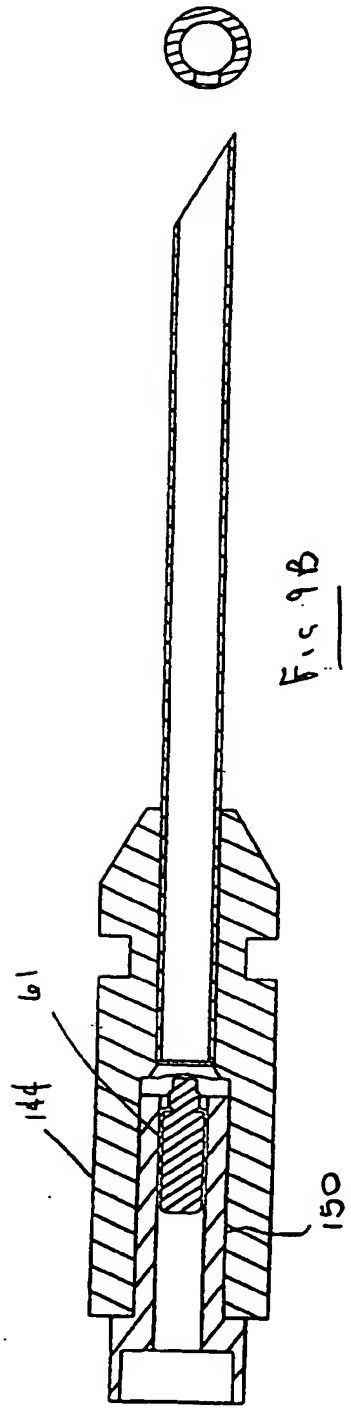

Fig 9B

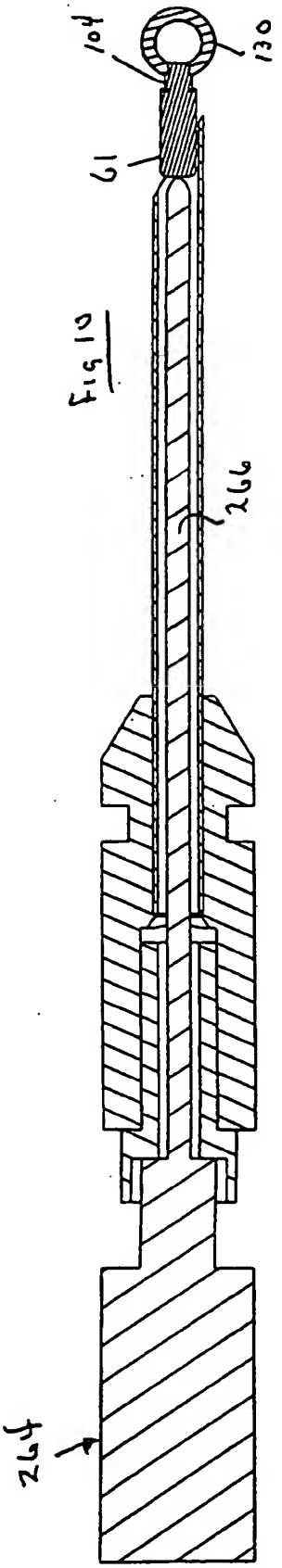

Fig 10

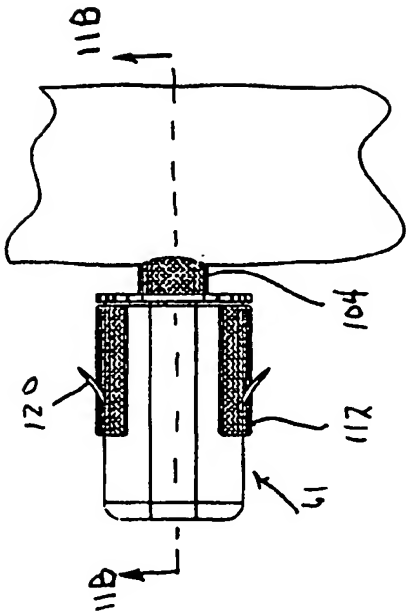

Fig 11A

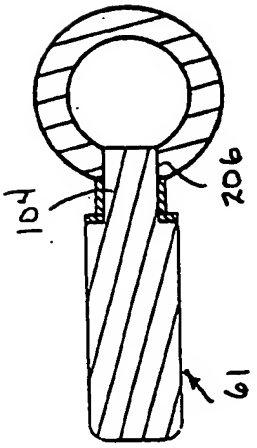

Fig 11B

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US04/041596

International filing date: 10 December 2004 (10.12.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/529,276
Filing date: 12 December 2003 (12.12.2003)

Date of receipt at the International Bureau: 26 January 2005 (26.01.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)